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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Knut BRABRAND	Group Art Unit: 3768
Application No.: 10/725,431	Examiner: Jaworski, Francis J.
Filed: December 3, 2003	Confirmation No.: 5321
For: RESPIRATION MONITOR	

Attention: Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPEAL BRIEF UNDER BOARD RULE § 41.37

In support of the Notice of Appeal filed July 3, 2007, and further to 37 C.F.R. 41.37(a)(1), Appellant presents this brief and encloses herewith a check for the fee of $500.00 required under 37 C.F.R. 41.20(b)(2).

This Appeal responds to the final rejection of claims 1-3, 6, 7, 9-14, and 17-21 mailed January 4, 2007 and to the Advisory Action mailed May 18, 2007.

If any additional fees are required or if the enclosed payment is insufficient, Appellant requests that the required fees be charged to Deposit Account No. 06-0916.

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I. Real Party in Interest

The real party in interest is NeoRad AS, the assignee of record.

II. Related Appeals and Interferences

There are currently no other appeals or interferences, of which Appellant, Appellant's legal representative, or the assignee are aware, that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

Claims 1-3, 6, 7, 9-14, and 17-21 are pending and stand rejected in this application. Claims 4, 5, 8, 15, and 16 have been cancelled.

Claims 1-3, 6, 7, 9-14, and 17-21 are being appealed.

The Examiner rejected claims 1, 6, 7, 14, 20, and 21 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,937,883 to Prince ("*Prince*") in view of U.S. Patent No. 5,355,887 to Iizuka et al. ("*Iizuka*"); rejected claims 2 and 3 under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, in view of *Iizuka*, and further in view of U.S. Patent No. 5,363,844 to Riederer et al. ("*Riederer*"); rejected claim 9 under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, in view of *Iizuka*, in view of *Riederer*, and further in view of U.S. Patent No. 4,431,007 to Amazeen et al. ("*Amazeen*"); rejected claim 10 under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, in view of *Iizuka*, and further in view of U.S. Patent No. 6,314,312 to Wessels et al. ("*Wessels*"); rejected claims 11, 12, and 17-19 under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, in view of *Iizuka*, and further in view of EP 0940158 A1 to Hernandez-Guerra et al. ("*Hernandez-Guerra*"); and rejected claims 1, 12, and 13 under 35 U.S.C. § 103(a) as being unpatentable over *Hernandez-Guerra*, in view of *Prince*, and further in view of *Iizuka*.

The final rejection of claims 1-3, 6, 7, 9-14, and 17-21 is being appealed and a list of the claims on appeal is found in the attached Claims Appendix.

Furthermore, each claim of this patent application is separately patentable, and upon issuance of a patent will be entitled to a separate presumption of validity under 35 U.S.C. § 282.

IV. Status of Amendments

All amendments have been entered. No amendments have been filed subsequent to the January 4, 2007 final Office Action.

V. Summary of Claimed Subject Matter

The invention relates generally to a method and apparatus for monitoring the degree of inspiration of a medical or surgical patient's lungs.

Independent claim 1 is directed to a method of determining the degree of lung inspiration in a patient comprising the step of non-invasively detecting the position of the patient's diaphragm. *See*, for example, specification at page 3, lines 15-18. The method is accomplished by means of an array of at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements. *See*, for example, specification at page 4, lines 15-21, page 5, lines 11-14, page 8, line 29 - page 9, line 3, and Fig. 1.

Independent claim 7 is directed to an apparatus for monitoring the position of a patient's diaphragm *See*, for example, specification at page 5, lines 2-10. The apparatus comprises an array of at least two ultrasound transducer elements for placing on the patient in the direction of the longitudinal (z) axis of the patient to extend over the lung sinus, wherein the position of the diaphragm may be determined based upon the difference between signals received by the individual transducer elements. *See*, for example, specification at page 5, lines 11-19, page 8, line 29 - page 9, line 3, and Fig. 1.

VI. Grounds of Rejection

A. Claims 1, 6, 7, 14, 20, and 21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,937,883 to Prince ("*Prince*") in view of U.S. Patent No. 5,355,887 to Iizuka et al. ("*Iizuka*").

B. Claims 2 and 3 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, in view of *Iizuka*, and further in view of U.S. Patent No. 5,363,844 to Riederer et al. ("*Riederer*").

C. Claim 9 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, in view of *Iizuka*, in view of *Riederer*, and further in view of U.S. Patent No. 4,431,007 to Amazeen et al. ("*Amazeen*").

A. Claim 10 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, in view of *Iizuka*, and further in view of U.S. Patent No. 6,314,312 to Wessels et al. ("*Wessels*").

B. Claims 11, 12, and 17-19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, in view of *Iizuka*, and further in view of EP 0940158 A1 to Hernandez-Guerra et al. ("*Hernandez-Guerra*").

C. Claims 1, 12, and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Hernandez-Guerra*, in view of *Prince*, and further in view of *Iizuka*.

VII. Argument

I. The rejection of claims 1, 6, 7, 14, 20, and 21 under 35 U.S.C. § 103(a) as being unpatentable over *Prince* in view of *Iizuka* is improper

The Examiner's rejection of claims 1, 6, 7, 14, 20, and 21 under 35 U.S.C. § 103(a) as being unpatentable over *Prince* in view of *Iizuka* should be reversed. The prior art cited by the Examiner does not teach or suggest each and every element of claims 1, 6, 7, 14, 20, and 21. For at least this reason, no *prima facie* case of obviousness has been established.

To establish a *prima facie* case of obviousness, the prior art, taken separately or in combination, must teach or suggest all the claim limitations. *See* M.P.E.P. § 2142, 8th Ed., Rev. 5 (August 2006). Moreover, "in formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed." USPTO Memorandum from Margaret A. Focarino, Deputy Commissioner for Patent Operations, May 3, 2007, page 2.

Claim 1 recites a method including:

> detecting the position of the patient's diaphragm by means of an array of at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements.

(emphasis added). *Prince* discloses a system control 122 that "receives a gating signal from an ultrasonic detector system 129" (col. 4, lines 50-51). "[D]etector system 129 receives an electrical signal from an ultrasonic transducer 11 that is positioned to sense motion in the patient" (col. 4, lines 52-54). *Prince* discloses "a transducer array

11 comprised of a plurality of separately driven elements 12 which each produce a burst of ultrasonic energy when energized by a pulsed waveform produced by a transmitter 13" (col. 5, line 67 - col. 6, line 3). This energy is reflected back to the transducer array 11 and is converted to an electrical signal.

The Examiner cites col. 10, lines 50-67 of *Prince* as allegedly constituting the claimed "at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements" (Final Office Action at page 2). This is not correct.

This passage of *Prince* discloses producing gate signals indicative of patient respiration "by locating the Doppler range gate across the diaphragm by aiming the ultrasound beam through the liver in a longitudinal orientation" (col. 10, lines 60-63). When the diaphragm moves, a signal is produced and "can be used to follow respiratory rate and rhythm" (col. 10, lines 66-67). Nothing in this passage or any other passage of *Prince* teaches or suggests the claimed "at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements," as recited in claim 1.

Prince does disclose a transducer array 11. However, even assuming that transducer array 11 corresponds to the claimed "at least two ultrasound transducer elements," which Appellant does not concede, *Prince* is silent regarding the claimed

"wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements," as recited in claim 1.

Iizuka fails to cure the deficiencies of *Prince*. *Iizuka* discloses "an ultrasonic diagnostic apparatus capable of . . . displaying the hardness of tissues of human body organs" (col. 2, lines 52-54). *Iizuka* discloses a single ultrasonic transducer 2 (Fig. 8). Nothing in *Iizuka* teaches or suggests the claimed "at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements."

In the Advisory Action, the Examiner asserted, "the linear array of Prince would function to provide signal difference information as evidenced by Iizuka et al." (Advisory Action at page 2). However, this is not correct.

Iizuka does not teach or suggest providing signal difference information using an array. On the contrary, *Iizuka* is silent regarding an array. Thus, there can be no teaching or suggestion in *Iizuka* of using an array to provide any signal difference information, and certainly no teaching of "at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements," as recited in claim 1.

Accordingly, no *prima facie* case of obviousness has been established with respect to claim 1, for at least the reason that the prior art, even in combination, fails to teach each and every element of the claim. The rejection under 35 U.S.C. §103 is therefore improper. Claims 6 and 14 depend from claim 1 and are thus also allowable over *Prince* in view of *Iizuka,* for at least the same reasons as claim 1.

Independent claim 7, though of different scope from claim 1, recites limitations similar to those set forth above with respect to claim 1. Claim 7 is therefore allowable for at least the reasons presented above. Claims 20 and 21 depend from claim 7 and are thus also allowable over *Prince* in view of *Iizuka,* for at least the same reasons as claim 7. Therefore, Appellant respectfully requests that the Board reverse the rejection of claims 1, 6, 7, 14, 20, and 21 under 35 U.S.C. § 103(a).

II. The rejection of claims 2 and 3 under 35 U.S.C. § 103(a) as being unpatentableover *Prince, Iizuka,* and *Riederer* is improper

The Examiner's rejection of claims 2 and 3 under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, *Iizuka*, and *Riederer* should be reversed. No *prima facie* case of obviousness has been established, at least because the prior art cited by the Examiner does not teach or suggest each and every element of claims 2 and 3.

Claims 2 and 3 depend from claim 1 and therefore include all of the elements recited therein. As noted above, *Prince* and *Izuka* fail to teach or suggest at least "detecting the position of the patient's diaphragm by means of an array of at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by

the individual transducer elements," as recited in claim 1 and required by claims 2 and 3. The Examiner states that "Riederer also teaches a calibration-breath-holding technique where the patient first assists in determining a diaphragm-stationary reference point . . ." (Final Office Action at page 3). Even assuming that this assertion is correct, which Appellant does not concede, *Riederer* fails to cure the deficiencies of *Prince* and *Iizuka*.

Riederer discloses "a breath-hold monitor which visually feeds back to the patient diaphragmatic position" (col. 2, lines 3-5). "[T]he invention includes a respiratory monitor which measures the patient's diaphragm position, a display which indicates diaphragm position to the patient during the scan, and means for triggering MRI data acquisition when a reference diaphragm position is maintained for a preset time forward" (col. 2, lines 7-13).

Riederer discloses neither the claimed "ultrasound transducer elements" to detect a diaphragm position, nor using "the difference between the signals received by the individual transducer elements" to determine the position of the diaphragm. Therefore, *Riederer* cannot teach or suggest "detecting the position of the patient's diaphragm by means of an array of at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements," as recited in claim 1 and required by dependent claims 2 and 3.

At least because the prior art fails to teach or suggest each and every element recited in independent claim 1 and required by dependent claims 2 and 3, no *prima*

facie case of obviousness has been established with respect to claims 2 and 3. Therefore, Appellant respectfully requests that the Board reverse the rejection of claims 2 and 3 under 35 U.S.C. § 103(a).

III. The rejection of claim 9 under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, *Iizuka*, *Riederer*, and *Amazeen* is improper

The Examiner's rejection of claim 9 under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, *Iizuka*, *Riederer*, and *Amazeen* should be reversed. No *prima facie* case of obviousness has been established, at least because the prior art cited by the Examiner does not teach or suggest each and every element of claim 9.

Claim 9 depends from claim 7 and therefore includes all of the elements recited therein. As noted above *Prince*, *Iizuka*, and *Riederer* fail to teach or suggest at least "an array of at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements," as recited in claim 7 and required by dependent claim 9. The Examiner admits that *Prince*, *Iizuka*, and *Riederer* do not teach "impedance change in the Z-direction with respect to diaphragm movement" (Final Office Action at page 3). However, the Examiner relies on *Amazeen* for allegedly teaching this claimed element (Final Office Action at pages 3-4).

Even assuming this allegation is true, which Appellant does not concede, *Amazeen* fails to cure the deficiencies of *Prince*, *Iizuka*, and *Riederer* discussed above. *Amazeen* discloses "an ultra-sound examination system which enables a real-time image, corresponding with the present location of a linear array or sector scan

transducer to be displayed, and which when the transducer is moved in either direction, continues to display static images of anatomy contiguous with a real-time image all on the same display device" (col. 2, lines 28-35).

Amazeen does not teach or suggest "an array of at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements," as recited in claim 7 and required by dependent claim 9.

At least because the prior art fails to teach or suggest each and every element recited in independent claim 7 and required by dependent claim 9, no *prima facie* case of obviousness has been established with respect to claim 9. Therefore, Appellant respectfully requests that the Board reverse the rejection of claim 9 under 35 U.S.C. § 103(a).

IV. The rejection of claim 10 under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, *Iizuka*, and *Wessels* is improper

The Examiner's rejection of claim 10 under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, *Iizuka*, and *Wessels* should be reversed. No *prima facie* case of obviousness has been established, at least because the prior art cited by the Examiner does not teach or suggest each and every element of claim 10.

Claim 10 depends from claim 1 and therefore includes all of the elements recited therein. As noted above, *Prince* and *Izuka* fail to teach or suggest at least "detecting the position of the patient's diaphragm by means of an array of at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis

of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements," as recited in claim 1 and required by claim 10. The Examiner asserts that "it would have been obvious in view of Wessels et al. . . . to track organ motion in association with biopsy in order that a small lesion such as P within the liver may be accurately targeted using the ultrasound as part of the tracking where ultrasound is used such as in Prince" (Final Office Action at pages 4). However, the Examiner's unsupported assertions do not alter the fact that *Wessels* fails to cure the deficiencies of *Prince* and *Iizuka* discussed above.

Wessels discloses "a method and a system that enable an adequately precise acquisition of the movement of an organ or body region, so that a therapist or operator is provided with exact knowledge with respect to the position of the organ or therapy region of interest" (col. 1, lines 46-50). However, *Wessels* does not teach or suggest "detecting the position of the patient's diaphragm by means of an array of at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements," as recited in claim 1 and required by dependent claim 10.

At least because the prior art, taken alone or in any reasonable combination, fails to teach or suggest each and every element recited in independent claim 1 and required by dependent claim 10, no *prima facie* case of obviousness has been established with

respect to claim 10. Therefore, Appellant respectfully requests that the Board reverse the rejection of claim 10 under 35 U.S.C. § 103(a).

V. The rejection of claims 11, 12, and 17-19 under 35 U.S.C.§ 103(a) as being unpatentable over *Prince*, *Iizuka*, and *Hernandez-Guerra* is improper

The Examiner's rejection of claims 11, 12, and 17-19 under 35 U.S.C. § 103(a) as being unpatentable over *Prince*, *Iizuka*, and *Hernandez-Guerra* should be reversed. No *prima facie* case of obviousness has been established, at least because the prior art cited by the Examiner does not teach or suggest each and every element of claims 11, 12, and 17-19.

Claims 11 and 17-19 depend from claim 7 and therefore include all of the elements recited therein. Claim 12 depends from claim 1 and therefore includes all of the elements recited therein. As noted above, *Prince* and *Izuka* fail to teach or suggest at least "detecting the position of the patient's diaphragm by means of an array of at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements," as recited in claim 1 and similarly recited in claim 7, and required by dependent claims 11, 12, and 17-19.

The Examiner states that *Prince* and *Iizuka* are "silent as to the use of an ultrasound-array-based non-invasive diaphragm position and motion tracking for radiation therapy" (Final Office Action at page 4). However, the Examiner relies on *Hernandez-Guerra* for allegedly teaching this claimed element (Final Office Action at pages 4-5).

Even assuming this allegation is true, which Appellant does not concede, *Hernandez-Guerra* fails to cure the deficiencies of *Prince* and *Iizuka* discussed above. *Hernandez-Guerra* discloses "a signal from a physiological monitor is used to generate a gating signal to gate the radiation beam at the optimal periods" (paragraph 0013).

Hernandez-Guerra does not teach or suggest "detecting the position of the patient's diaphragm by means of an array of at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements," as recited in claim 1 and required by dependent claim 12. Moreover, *Hernandez-Guerra* does not teach or suggest "an array of at least two ultrasound transducer elements for placing on the patient in the direction of the longitudinal (z) axis of the patient to extend over the lung sinus, wherein the position of the diaphragm may be determined based upon the difference between signals received by the individual transducer elements," as recited in claim 7 and required by dependent claims 11 and 17-19.

At least because the prior art fails to teach or suggest each and every element recited in independent claims 1 and 7 and required by dependent claims 11, 12, and 17-19, no *prima facie* case of obviousness has been established with respect to claims 11, 12, and 17-19. Therefore, Appellant respectfully requests that the Board reverse the rejection of claim 11, 12, and 17-19 under 35 U.S.C. § 103(a).

VI. The rejection of claims 1, 12, and 13 under 35 U.S.C. § 103(a) as being unpatentable over *Hernandez-Guerra*, *Prince*, and *Iizuka* is improper

The Examiner's rejection of claims 1, 12, and 13 under 35 U.S.C. § 103(a) as being unpatentable over *Hernandez-Guerra*, *Prince*, and *Iizuka* should be reversed. No *prima facie* case of obviousness has been established, at least because the prior art cited by the Examiner does not teach or suggest each and every element of claims 1, 12, and 13.

As established above, neither *Prince* nor *Iizuka* teach or suggest the claimed "at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements," as recited in claim 1. *Hernandez-Guerra* fails to cure the deficiencies of *Prince* and *Iizuka*.

Hernandez-Guerra discloses "a signal from a physiological monitor is used to generate a gating signal to gate the radiation beam at the optimal periods" (paragraph 0013). *Hernandez-Guerra* does not teach or suggest "detecting the position of the patient's diaphragm by means of an array of at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements," as recited in claim 1.

Accordingly, the prior art fails to establish a *prima facie* case of obviousness with respect to claim 1, at least since the references fail to teach each and every element of

the claim. Claims 12 and 13 depend from claim 1 and are thus also allowable over *Hernandez-Guerra*, *Prince*, and *Iizuka,* for at least the same reasons as claim 1. Therefore, Appellant respectfully requests that the Board reverse the rejection of claims 1, 12, and 13 under 35 U.S.C. § 103(a).

CONCLUSION

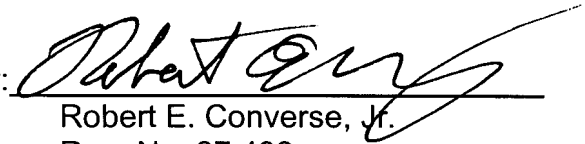
For at least the reasons given above, pending claims 1-3, 6, 7, 9-14, and 17-21 are allowable over the applied prior art. Therefore, Appellant respectfully requests the Board to reverse the Examiner's rejection of claims 1-3, 6, 7, 9-14, and 17-21 under 35 U.S.C. § 103(a).

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: September 4, 2007

By: 
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VIII. Claims Appendix to Appeal Brief Under Rule 41.37(c)(1)(viii)

1. A method of determining the degree of lung inspiration in a patient comprising the step of non-invasively detecting the position of the patient's diaphragm by means of an array of at least two ultrasound transducer elements on the patient extending in the direction of the longitudinal (z) axis of the patient over the lung sinus, wherein the position of the diaphragm is determined based upon the difference between the signals received by the individual transducer elements.

2. A method as claimed in claim 1, wherein the diaphragm position is used as a reference point to define the degree of lung inspiration when an image of the patient is generated and further comprising the step of reproducing that degree of lung inspiration in order to perform a medical or surgical procedure on the patient based on that image.

3. A method as claimed in claim 2, wherein the diaphragm position is first determined whilst the patient holds his breath and images are generated simultaneously therewith, the degree of lung inspiration subsequently being reproduced by the patient inhaling or inhaling and exhaling until the previously determined diaphragm position is achieved and the desired procedure being then carried out whilst the patient holds his breath.

4. (Cancelled)

5. (Cancelled)

6. A method as claimed in claim 1, wherein the array of ultrasound transducer elements is placed on the patient's lower chest and/or upper abdomen and is moved into a desired position over the lung sinus using feedback from the ultrasound transducer elements.

7. An apparatus for monitoring the position of a patient's diaphragm comprising an array of at least two ultrasound transducer elements for placing on the patient in the direction of the longitudinal (z) axis of the patient to extend over the lung sinus, wherein the position of the diaphragm may be determined based upon the difference between signals received by the individual transducer elements.

8. (Cancelled)

9. An apparatus as claimed in claim 7, wherein the measured acoustic impedance from each transducer element is used as an input to a processor and acoustic impedance may be processed to provide a function that varies with the movement of the diaphragm in the z-direction.

10. A method of performing a biopsy using the method of claim 1.

11. A method of radiotherapy comprising providing a source of radiation and directing it at a target area of a patient, wherein the emission of the radiation beam is triggered by means of an apparatus according to claim 7.

12. A method of radiotherapy comprising providing a source of radiation and directing it at a target area of a patient, wherein the emission of the radiation beam may be controlled to follow the movement of the target based on the position of the diaphragm as determined by the method of claim 1.

13. A radiotherapy apparatus comprising a radiation source and a control unit, the source being mounted on a tracking device and being controlled by a control unit to direct the radiation towards the calculated position of the tumor based on the current measurement of diaphragm position obtained by the method of claim 1.

14. A method of monitoring respiration by monitoring the movement of a patient's diaphragm using the method of claim 1.

15. (Cancelled)

16. (Cancelled)

17. A method of performing a biopsy using the apparatus of claim 7.

18. A method of radiotherapy comprising providing a source of radiation and directing it at a target area of a patient, wherein the emission of the radiation beam may be controlled to follow the movement of the target based on the position of the diaphragm as determined by the apparatus of claim 7.

19. A radiotherapy apparatus comprising a radiation source and a control unit, the source being mounted on a tracking device and being controlled by a control unit to direct the radiation towards the calculated position of the tumor based on the current measurement of diaphragm position obtained by the apparatus of claim 7.

20. A method of monitoring respiration by monitoring the movement of a patient's diaphragm using the apparatus of claim 7.

21. An apparatus as claimed in claim 7, wherein the array of transducer elements is a one-dimensional array.

IX. Evidence Appendix to Appeal Brief Under Rule 41.37(c)(1)(ix)

None.

X. Related Proceedings Appendix to Appeal Brief Under Rule 41.37(c)(1)(x)

None.